

**Title: Overview of the Human Research Protection Program at Lawrence Livermore
National Laboratory**

Standard Operating Procedure: # 1

Department: Human Research Protection Program/Institutional Review Board

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Subject: Human Research Protection Program

Policy:

It is the goal of Lawrence Livermore National Laboratory (LLNL) to ensure that all research involving humans as participants, conducted under the auspices of LLNL, complies with all federal and state laws, as well as Lawrence Livermore National Security, LLC, policies regarding the protection of human subjects in research. As described in its Federalwide Assurance of Compliance (FWA00004274) with the Office of Human Research Protections (OHRP), LLNL has elected to apply the Common Rule (45 CFR 46) and the principles of the Belmont Report to all human subjects research in which it is engaged, regardless of sponsorship.

The protection of human subjects in all the research performed under Department of Energy (DOE) authorities is of prime importance to the Department. All research conducted at DOE institutions, supported with DOE funds, or performed by DOE employees, including research that is classified and proprietary, whether done domestically or in an international environment, must comply with all federal regulations and DOE requirements that address the protection of human subjects.

Lawrence Livermore National Laboratory follows the program prescribed by the U.S. Department of Energy as shown in <http://humansubjects.energy.gov/>.

The *Human Subjects Protection Resource Book* is an attempt to synthesize the information currently available on the protection of human subjects in research, the continuing application of such information to new areas of endeavor, and the ever-changing rules, regulations, and guidance involved in the hope that it might provide useful information for investigators, Institutional Review Boards (IRBs), research organizations, research subjects, and others.

The resource book contains chapters that provide background information on the history and development of the federal regulations, chapters that discuss procedural and substantive issues regarding the review and conduct of human subjects research, and chapters that are specific to one type of research (e.g., genetics, biological samples) or research in specific populations (e.g., international settings, children, and workers).

The resource book was a joint project of several agencies: DOE, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. However, this manual does not represent the official views or policies of any of these or any other agencies.

The resource book may be downloaded (PDF version) by accessing the following link:
<http://humansubjects.energy.gov/doe-resources/humsubj-resourcebook.htm>

The Deputy Director of LLNL is the Human Research Protection Program's Authorized Institutional Official (AIO). The Human Research Protection Program consists of the LLNL IRB committee and the LLNL Human Research Protection Program Office, which coordinates the activities of the IRB committee.

As required by federal and state laws, all human subjects research conducted under the auspices of LLNL shall be reviewed and approved by the LLNL IRB. The AIO or designee may approve or disapprove a study that has been approved by the LLNL IRB. However, the AIO or designee may **not** approve a study that has not been approved by the LLNL IRB.

References:

45 CFR 46

Department of Energy, Human Subjects Protection Program